

REMARKS**Status of the Claims**

Claims 56-57, 60, and 62-64 are amended, and claims 61 and 66 are cancelled without prejudice or disclaimer. New claims 69 is added, which finds support in the specification on page 6, line 21-26. No new matter has been added.

Response to Restriction

In the Office Action of July 2, 2003, the examiner has withdrawn claims 55, 57-58, 63-65, and 67-68 on the basis that “the claims are drawn to an invention not elected in the response to the restriction requirement filed 7/22/2002. See 37 CFR 1.142(b) and MPEP 821.03.” *See* Office Action, page 2, item 2. Applicants respectfully traverse this restriction requirement.

The present invention was filed under 35 USC § 371, and therefore, this application should be evaluated under the standard of unity of invention. Applicants respectfully direct the examiner’s attention to PCT Rule 13.1 MPEP, Annex B, paragraph (c), wherein it states:

“unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims.”

Furthermore, “if the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if the dependent claim itself contains a further invention.” *See* MPEP, Annex B, paragraph c(i).

Applying the rules for unity of invention, applicants submit that the present restriction is improper. Specifically, claims 55 and 63, and 67-68 (and their respective dependent claims 57-58 and 64-65) depend from elected independent claims, and therefore should be elected under the provisions of PCT Rule 13.1. Accordingly, applicants respectfully request withdrawal of the restriction requirement.

Information Disclosure Statement

The examiner has indicated that applicants have not submitted Australian Patent No. 48747/97. The examiner acknowledges receipt of Australian Patent No. 730900. *See* Office Action, page 3, item 7.

Applicants respectfully submit that Australian Patent Application No. 48747/97 is the application number for granted Australian Patent No. 730900. These documents are essentially the same, only the number has changed. In accordance with Australian practices, applications are given a number (*e.g.* 48747/97) at the time of filing and a serial number (*e.g.* 730900) upon acceptance.

Rejections- 35 U.S.C. § 112, Second Paragraph

Claims 56, 60-61, and 66 are rejected under 35 U.S.C 112, second paragraph, for alleged indefiniteness. See Office Action, page 3-4, item 8. As there are numerous indefinite rejections, each rejection is enumerated below.

Claim 56 has been rejected on the grounds that “the term altering is unclear.” Similarly, claim 66 has been rejected on the basis that “the term altered is unclear.” Applicants respectfully traverse these rejections on the basis that a claim is sufficiently definite to satisfy the statutory requirement of 35 U.S.C. § 112, second paragraph, if one of ordinary skill in the art would understand the bounds of the claim when read in light of the specification. Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993). Most importantly here, a claim is definite if it is amenable to construction, however confusing that task may be. Exxon, 265 F.3d at 1375, 60 USPQ2d at 1276. In other words, if the meaning of the claim is discernible, the claim avoids a rejection on indefiniteness grounds. Id.

In this rejection, claims 56 and 66 are amenable to claim construction, since the meaning of “altering” and “altered” are available from dictionaries. Since the meaning of claims 56 and 66 are discernible, claims 56 and 66 avoid rejection on indefiniteness grounds. Thus, the rejections should be withdrawn.

Claim 60 has been rejected on the grounds that “propagating material” is allegedly indefinite. The present version of claim 60 avoids this issue. Accordingly, applicants respectfully request reconsideration and withdrawal of the rejection.

Rejections- 35 U.S.C. § 101

Claims 48-54, 56, 59-62, and 66 are rejected under 35 U.S.C. 101 for alleged lack of utility. Specifically, the examiner contends that “a closer look at the presented data only indicates that 13 of the 768 amino acids of SEQ ID NO:12 share identity with the N-terminal

region of other starch branching enzymes, and given that it has not been disclosed if the catalytic site of the starch branching enzyme is contained in the N-terminal region of the polypeptide, and given that Applicants isolated their invention by weak sequence hybridization to a maize starch branching enzyme II, and given that Applicants have not verified the starch branching activity of their polypeptide, Applicant's invention is not supported by either a credible asserted utility or a well established utility." Applicants respectfully traverse this rejection.

As indicated in the Amendment filed April 24, 2003, Applicants submit that SEQ ID NO: 10 shares homology to other SBE II sequences *and* encodes a translation product (SEQ ID NO: 12) with characterized SBE II activity. The examiner is directed to commentary from Example 14, at page 37 of the specification:

Sequencing of the SBE II gene contained in clone 2, termed SBE II-D1 (see SEQ ID NO: 10), showed that it coded for the N-terminal sequence of the major isoform of SBE II expressed in the wheat endosperm, as identified by Morell *et al* (1997). This is show in Figure 13.

Thus, Example 14 indicates that the translation product of SEQ ID NO: 10 is the same protein reported by Morell *et al.* (1997). As described in their publication, Morell and colleagues identified the protein after purifying it on the basis of its having starch branching enzyme activity. See pages 202-203 and Table II on page 205. In other words, the knowledgeable reader of the present specification is informed that the translation product of SEQ ID NO. 10 has defined SBE II activity. Applicants therefore request reconsideration and withdrawal of the rejections.

The evidence and explanation of record is further supplemented by the Declaration of Dr. Sadequr Rahman. According to Declarant Rahman, the SBE II gene, represented by the clone SBE-9 (See Specification, Example 13, page 36) has about 97% sequence identity with the coding region of SEQ ID NO:10 and was subsequently shown to have SBE activity. SBE activity for SBE-9 was reported in Rahman *et al.* (2001), where the clone is designated cDNA1. A copy of Rahman *et al.* (2001) is enclosed for consideration.

Specifically, the examiner is directed to page 1316, left-hand column of Rahman *et al.* (2001), wherein it states:

“However, cDNA1 encodes a functional branching enzyme as it could complement *Escherichia coli* mutants lacking branching enzyme due to the *glgB* mutation (data not shown).”

In view of the reasons advanced above and set forth in the Declaration of Dr. Rahman, the knowledgeable reader of the present specification is informed that the translation product of SEQ ID NO: 10 has defined SBE II activity.

Rejections- 35 U.S.C. § 112, first paragraph (written description)

Claims 48-50, 52-54, 56, 59-62, and 66 are rejected under 35 U.S.C. 112, first paragraph, for alleged lack of written description. The examiner bases this rejection on the grounds that “applicants have not fully described the genus which would include for example, those amino acids involved in the catalytic domain(s) of the enzyme.” See Office Action, pages 5-6, item 11.

Applicants respectfully traverse this rejection. According to MPEP § 2163, the examiner has the initial burden of presenting evidence why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined by the claims. As the examiner even admits, applicants have disclosed “structural features of the wheat endosperm SBE II gene, including the promoter.” See Office Action, page 6. Yet the rejection is maintained on the grounds that applicants have not, for example, provided the amino acids involved in the catalytic domain(s).

According to the U.S. Patent and Trademark Office Guidelines for Written Description, the examiner must consider identifying characteristics of an inventive nucleotide or amino acid sequence, such as disclosure of partial structure, functional characteristics, known or disclosed correlation between structure and function, and physical and/or chemical properties. Disclosure of any of these characteristics, or combination thereof, sufficiently meet the requirements for written description. See Guidelines for Written Description, page 8. At a minimum, applicants have disclosed a partial sequence, functional characteristics, and correlations between structure and function. Accordingly, the rejection is improper and should be withdrawn.

Claims 48-50, 52-54, 56, 59-62, and 66 are rejected under 35 U.S.C. 112, first paragraph, for alleged lack of written description. Specifically, the claims are rejected on the

grounds that “SBE II gene comprises 22 exons which are encoded by genomic sequence base numbers 1058 to 11475, but applicants only disclose 11463 bases in SEQ ID NO: 10.” See Office Action, pages 5-6, item 11.

Applicants have amended the specification to reflect the correct length of SEQ ID NO: 10. Therefore, applicants disclose the full genomic sequence and are in possession of the claimed invention. Accordingly, the rejection is improper and should be withdrawn.

Rejections- 35 U.S.C. § 112, first paragraph (enablement)

Claims 48-54, 56, 59-62, and 66 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Office Action, pages 6-7. Applicants respectfully traverse this rejection.

For the reasons advanced above, and as supplemented by the Declaration of Dr. Rahman, the claimed subject matter is supported by an enabling disclosure. Specifically, the translation product encoded by SEQ ID NO: 10 was identified based on its having SBE II activity and has several structural and functional domains characteristic of SBE II proteins.

Furthermore, Dr. Rahman corroborates that plants transformed with SEQ ID NO: 10 in the antisense orientation have reduced SBE II enzyme expression and altered starch content. According to Dr. Rahman, the isolated nucleic acids of the invention may be used according to the teaching of the specification to alter SBE II activity and starch in a plant.

Therefore, the specification provides full disclosure to guide a person skilled in the art to make and use the present invention. For this reason, applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the examiner, placing the claims in condition for allowance. Applicants submit that the proposed claim amendments neither raise new issues nor necessitate the undertaking of any additional search of the art by the examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the examiner.

Finally, applicants submit that the entry of the amendment would place the application in better form for appeal.

If there are any questions concerning this application, the examiner is courteously invited to contact the undersigned counsel.

Respectfully submitted,

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